510(k) SUMMARY

Abdominal Aortic and Junctional Tourniquet – K133029

Submitter's Name and Address:

John Croushorn, M.D.
Compression Works LLC
1634-A Montgomery Hwy #115
Hoover, AL 35216

Telephone: 205-202-1126
e-mail: jcroushorn@gmail.com

DEC 0 6 2013

Date of Preparation: November 12, 2013

Contact Person

Michael S. Forstadt
Consultant to Compression Works LLC

Telephone: 401-521-3294
e-mail: rcforstadt@hotmail.com

Name of Medical Device

Classification Name: Vascular clamp

Common/Usual Name: Vascular clamp

Proprietary Name: Abdominal Aortic and Junctional Tourniquet

Substantial Equivalence

The Abdominal Aortic and Junctional Tourniquet is substantially equivalent to:

Compression Works Abdominal Aortic Tourniquet (AAT) device (K112384), the Combat Medical Systems, LLC's Combat Ready Clamp (CRoC) (K130482) and the SAM Junctional Tourniquet (K131561).

Device Classification

This device, a vascular clamp carries an FDA product code DXC, regulated under 21 CFR 870.4450.

Device Description

The Abdominal Aortic and Junctional Tourniquet (AAJT) is designed to be used by military medical personnel in the battlefield to control bleeding in the pelvis, inguinal area and axilla where standard tourniquets cannot be used. The device may be used instead of

"mechanical pressure", allowing the medic to attend to other injuries or soldiers.

Indications for Use

The Abdominal Aortic and Junctional Tourniquet (AAJT) is indicated for use in the battlefield to control difficult bleeding in the pelvis, inguinal area and axilla.

Technological Comparison to Predicate Devices

	Proposed AAJT Device	Predicate AAT Device
Configuration	Inflatable pneumatic tourniquet	Inflatable pneumatic tourniquet
Method of Action	Manual	Manual
Components	Waistband (belt and cumberband), inflatable air bladder (pneumatic inflator), manual pump	Waistband (belt and cumberband), inflatable air bladder (pneumatic inflator), manual pump

Performance Testing

Results of performance testing have demonstrated that the device is substantially equivalent to the predicate devices.

A human data study in thirteen (13) subjects showed that in all subjects (13/13) the blood flow in both the PFA and the AA were stopped as measured by no spectral Doppler flow in the distal artery. Bladder pressure at zero Doppler flow at the PFA was 148.5 mm Hg (SD 44.8, maximum 230, minimum 80) and at the AA was 168 mm Hg (SD 52.5, maximum 250, minimum 80). Pain averaged a maximum of 3.6 and 4.1 at flow cessation for the PFA and AA respectively and returned to 0 after device removal.

The Abdominal Aortic and Junctional Tourniquet (AAJT) with the additional indications (to control difficult bleeds in the pelvis and axilla area) is substantially equivalent to the predicate AAT device cleared under K112384. It has equivalent design and materials, addresses the same patient population, has the same mechanism of action and uses no new technology. The new indication does not introduce new safety or performance concerns, and is similar to that of the predicate Combat Ready Clamp and SAM Junctional Tourniquet. Therefore, based on the indications for use, technological characteristics, and comparison to

predicate devices, the Abdominal Aortic and Junctional Tourniquet has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Compression Works, LLC
c/o Michael Forstadt
Consultant to Compression Works, LLC
15 Sargent Ave
Providence, RI 02906 US.

Re: K133029
Trade/Device Name: Abdominal Aortic and Junctional Tourniquet
Regulation Number: 21 CFR 870.4450
Regulation Name: Clamp, Vascular
Regulatory Class: Class II
Product Code: DXC
Dated: September 23, 2013
Received: October 15, 2013

Dear Mr. Forstadt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133029

Device Name: Abdominal Aortic and Junctional Tourniquet

Indications for Use:

The Abdominal Aortic and Junctional Tourniquet is indicated for use in the battlefield to control difficult bleeds in the pelvis, inguinal area and axilla.

Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
2013.12.06 15:04:14
-05'00'